DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103663/5011

NOV 4 2002

InterMune, Incorporated
Attention: Marianne Armstrong
Senior Vice President, Global Regulatory
Operations and Corporate Compliance
3280 Bayshore Boulevard
Brisbane, CA 94005

Dear Ms. Armstrong

Your request to supplement your biologics license application for Interferon alfacon-1, to provide a Medication Guide, has been approved.

Pursuant to 21 CFR Part 208, FDA has determined that this product poses a serious and significant public health concern requiring the distribution of a Medication Guide. Interferon alfacon-1 is a product for which patient labeling could help prevent serious adverse effects and inform the patient of serious risks relative to benefit that could affect their decisions to use, or continue to use, the product. Therefore, a Medication Guide is necessary for safe and effective use of this product and FDA hereby approves the draft Medication Guide you submitted November 4, 2002. Please note that the final printed Medication Guide must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text. Additionally, in accordance with 21 CFR 208, you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product. You are also responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Karen D. Weiss, M.D.
Director
Division of Clinical Trial Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research